K130309

JUN 17 2013

510(k) Summary

June 11, 2013

Contact: Biomet Microfixation
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Jacksonville, FL 32218
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Telephone: 904-741-9465
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Common of Usual Name: Cover, Burr hole

Classification Name: 882.5250 – Burr hole cover

Device Classification: Class II

Device Product Code: GXR

Device Name: RapidFlap™ LS Cranial Fixation Flap System

Indications for Use / Intended Use: The RapidFlap™ LS Cranial Flap Fixation System is indicated for use in rigid fixation of a craniotomy in adult and pediatric populations.

Contraindications: 1. Active infection; 2. Patient conditions including blood supply limitations, insufficient quantity or quality of bone stock or latent infection; 3. DO NOT USE in patients with a decompression flap.

Description: The RapidFlap™ LS Cranial Flap Fixation System is comprised of three parts, an inner plate, an outer plate and a central post. The inner plate consists of a circular disk through which the post is centrally extruded outwardly. The outer plate consists of a circular disk which a threaded hole to accept the post. The devices are assembled by hand to force the plates together capturing the bone. When applied, the plates tightly grip the bone flap, and provide rigid attachment and coplanar alignment to the surrounding bone. The RapidFlap™ LS System is made from Polylactic / polyglycolic acid copolymer.

The LactoSorb® Heat /Contouring Pen is a disposable alkaline-battery powered device. Two tips are provided with the body or handle of the device. These tips can use the same handle to perform slightly different functions. The long wire tip is used to cut the LactoSorb® plates and the flat surfaced tip is used to smooth the edges of the plates. The device is supplied sterile.

Sterility Information: The LactoSorb® implants are sterilized by exposure to Ethylene Oxide (ETO) Gas.

Substantial Equivalence: The RapidFlap™ LS Cranial Fixation System is substantially equivalent to the LactoSorb® RapidFlap™ System (K003281), Aesculap CranioFix Abosorbable Device (K021408 & K040080) and the Synthes Rapid Resorbable Clamp (K041611). Substantial equivalence was not based on nonclinical or clinical data. The following comparison table shows that all devices are similar in design, material, sterilization and intended use. The purpose of this submission is only to include adult populations in the current indications for use, which is consistent with predicate devices shown below.

	Aesculap CranioFix Abosorbable Device (K021408 & K040080)	**Synthes Rapid Resorbable Clamp (K041611)**	**LactoSorb® RapidFlap™ System (K003281)**	**RapidFlap™ LS Cranial Fixation System (subject device)**
Material	Poly (L/DL-lactide)	85:15 poly (L-lactide-co-glycolide)	Polylactic / polyglycolic acid copolymer	Polylactic / polyglycolic acid copolymer
Material property	Resorbable	Resorbable	Resorbable	Resorbable
Indications for Use	Covering burr holes and fixation of cranial bone flaps	Covering burr holes and fixation of cranial bone flaps in adult and pediatric populations	Pediatric craniotomy flap fixation	Rigid fixation of a craniotomy in adult and pediatric populations
Use	Craniotomy procedures	Craniotomy procedures	Craniotomy procedures	Craniotomy procedures
Sterility	Sterile	Sterile	Sterile	Sterile
Components	11mm, 16mm & 20mm clamps	18mm Clamp	14mm Clamp	14mm Clamp
Component description	Two disks connected by a ratcheting shaft	Two disks connected by a tensioned ratcheting shaft	Inner and outer plates (each consisting of a circular disk with a threaded hole) connected by a threaded central post	Inner and outer plates (each consisting of a circular disk with a threaded hole) connected by a threaded central post

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2013

Biomet Microfixation
% Ms. Christine Scifert
Managing Partner
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, TN 38133

Re: K130309
Trade/Device Name: RapidFlap™ LS Resorbable Cranial Flap Fixation System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: March 20, 2013
Received: March 21, 2013

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130309

Device Name: RapidFlap™ LS Resorbable Cranial Flap Fixation System

Indications For Use:

The RapidFlap™ LS Cranial Flap Fixation System is indicated for use in rigid fixation of a craniotomy in adult and pediatric populations.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
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(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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